EVALUATION OF QUALITY MEASURES FOR POINT OF CARE BLOOD GLUCOSE TESTING AT KENYATTA NATIONAL HOSPITAL

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A DISSERTATION SUBMITTED IN PARTIAL FULFILMENT OF THE REQUIREMENTS FOR THE AWARD DEGREE OF MASTERS OF SCIENCE IN CLINICAL CHEMISTRY

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I, Fridah Muthoni Mukunya, registration number H58/11022/2018 declare that this research dissertation is my original work and has not been obtained from any other source other than the sources cited.

Signature  Date 5th September 2022

SUPERVISORS' DECLARATION

We confirm that this dissertation was written by the above-named student and has been submitted with our approval as supervisors.

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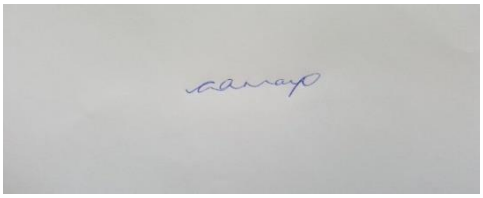

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DEDICATION

To my mum, friends and supervisors who supported me as I worked on this project

ACKNOWLEDGEMENTS

I thank the Almighty God for His many blessings during this journey

I thank my mum for her endless support

I sincerely thank my supervisor Professor Amayo for her commitment and support.

I also thank the Kenyatta National Hospital for according me the permission to carry out this research study and sponsoring me for this study.

I also thank all the nurse managers and nurses who accepted to be part of this study.

LIST OF ABBREVIATIONS

BC- before Christ

BGM- blood glucose monitor

CAP-the college of American pathologists

CCU- critical care unit

CLIA- clinical laboratory improvement amendments

CLIS- clinical and laboratory standards institute

CMS- centres for medicare and medicaid services

CoA- certificate of accreditation

CoC- CLIA certificate of compliance

CV- coefficient of variation

DKA- diabetes ketoacidosis

DM- diabetes mellitus

EQA- external quality assurance

EN- European norm

FDA- food and drug administration

GLP- good laboratory practice

ICU- intensive care unit

ISO-international organization for standardization

IQA- internal quality assurance

IQC- internal quality control

KNH- Kenyatta national hospital

MOH- ministry of health

MLS- millitres

NASCOP- national AIDS STI control program

NBU- newborn unit

NICU- neonatal intensive care unit

PICU- Pediatric intensive care unit

POC- point of care

POCT- point of care testing

POCD- point of care device

QA- quality assurance

QC- quality control

QMS- quality management system

RBC- red blood cells

SBGM- self blood glucose monitoring

SD- standard deviation

SOPs- standard operating procedures

$- dollars

TAT- turnaround time

UON- University of Nairobi

US- United States

USA- United States of America

Table of Contents

LIST OF FIGURES

LIST OF TABLES

ABSTRACT

Background: Point of Care Testing (POCT) is defined as a type of laboratory testing that is done close to the patient as opposed to laboratory testing in the hospital's main laboratory (Shaw, 2015). It is estimated that the POCT market will grow from United States (US) dollars ($) 23.16 in 2016 to US$ 36.96 billion in 2021(Vashit, 2017). Blood glucose is one of the most common POC tests (AACC, 2015). According to Klonoff (2017), POCT is not only used in the determination of blood glucose levels in hospitalized patients but it is also used to make quick medical decisions in response to altered glycemic states. Standards for POCT performance have been established to ensure quality of the results.

Objective: To evaluate the quality measures put in place in Kenyatta National Hospital (KNH) to ensure accurate glucose results.

Methodology: This was a mixed method study. It was a descriptive cross sectional and phenomenological study to be conducted in the wards on levels 1,3,4,5,6,7,8,9,10, labour ward, GFA, newborn unit (NBU), neonatal intensive care unit (NICU), burns unit, critical care units (CCUs) on the 7th and 8th floor and renal ward; where POC blood glucose testing was done at the KNH. These areas were not under central laboratory management. Study participants included nurse's performing POC blood glucose tests, as well as nurse managers of the wards. Qualitative data was collected from the nurse managers using a phenomenological tool. For quantitative data collection, the nurses performed POC glucose tests after being given a questionnaire to fill and commercial glucose quality control (QC) material was requested to be analyzed by them on the glucose meter like patient samples.

Sample size and sampling procedures: For the cross-sectional study, a total of 230 nurses were selected via convenience sampling, where the nurses on duty at the time were approached and invited to enroll into the study, if they met the inclusion criteria. This was done consecutively till five nurses are enrolled at each site. For the qualitative study, a total of 12 nurse managers were selected by convenience sampling. The nurse manager on duty at the study site was approached and invited to participate in the study. This was done in each site until the sample size was achieved.

Data analysis: Data analysis for quantitative data for both the questionnaires and quality control findings were performed using statistical package for social science (SPSS) version 20.0.

The data from the questionnaires was presented in tables, bar graphs and pie charts

Results of quality control analysis were compared with set target values for analysis of accuracy. Data was presented in line graphs.

The researcher analyzed the qualitative data. The data was presented as themes.

Results: 230 nurses and 12 nurse managers participated in the study

The quantitative data collected from the 230 nurses looking at various aspects such as training, policies/guidelines put in place for POCT blood glucose testing and quality assurance practices.

On glucometer training in KNH, it was found out that 43.0% (*n*=99) of the respondents have been trained on how to use glucometer at KNH. Majority of the participants had not been trained.

It was also demonstrated that there was not a well defined quality management system in KNH that encompasses quality policies, SOPs, safety issues and quality assurance

It was also demonstrated that only 16.1% (n=37) nurses had heard about the policies ISO 15189 and ISO 22870 that makeup the quality management system guideline and POCT accreditation requirements. On enquiry whether the nurses had an SOP to guide glucose testing using a glucometer 58.3% (n=134) said there was none. Less than a third <33.3% (<n=76) of the respondents ever heard of the terms IQC and EQA. Nurse Managers, on the other hand, using the phenomenological tool demonstrated that they had no knowledge on POC policies/guidelines and they did not quite fully understand their role in POC blood glucose testing

For quality control results using the assigned mean, collectively 12 participants were found to be outside ± 3SD. When using the consensus mean, collectively 7 participants were found to be outside ±3SD.

Conclusions: The BGMs in use at KNH meet required performance specifications.

There is no policy document guiding POC glucose testing at KNH. Only 40% sites had an SOP for glucose testing

Only 43% BGM users had received training. Training is not standardized, and trainees are not certified.

CHAPTER ONE

1.0 INTRODUCTION

POC testing is any test performed near a patient or at the site where treatment is being offered (AACC, 2015). POCT was first used in 1550 before Christ (BC) where physicians used ants to diagnose glycosuria in patients suspected to have diabetes (Rajendran and Rayman, 2014). According to the global POCT market research report (2019),point-of-care testing is expected to grow at 9.3% over the next five years globally, to reach 30000 million US$. Glucose tests make the largest contribution to the POCT growth because of increasing global prevalence of diabetes, with attendant increase in home based glucose testing.

The prevalence of diabetes among Kenyan adults was about 3.6% in 2013 and is expected to increase to 4.4% in 2035 (Guariguata, 2014). The Kenya national guidelines for management of diabetes mellitus (2010), recommend for self-blood glucose monitoring (SBGM) where possible.

Portable blood glucose meters are devices that measure blood glucose in small blood specimens usually blood collected from a fingertip. Blood glucose monitors (BGMs) were initially developed for home use but with technological development the devices were introduced into the hospital setting (Monjelat et al., 2018). Point of care devices (POCD) have become important in monitoring of glycemic states because they are available near the patient (Rajendran and Rayman, 2014).

According to the United States food and drug administration (FDA, 2019) glucometers can be used in health care facilities to improve management of diabetic patients in ways including; determination of daily treatment adjustments and identification of severe hypoglycemia or hyperglycemia.

Errors in testing using BGM would lead to inappropriate patient management hence the need to maintain accuracy of the machines (FDA, 2017). Studies have shown that improved accuracy in these meters is associated with reduction in insulin-induced hypoglycemia (Klonnof, 2014). Another study showed that BGM operator error occurred frequently and total error rate was related to familiarity with quality control procedures in BGM (Corl, 2012)

Laboratory and nursing personnel should establish quality assurance practices such as calibration of the BGM, adequate training and comparison of meter results with a central laboratory result (Weitgasse et al., 2007).

The aim of this study was to describe the measures taken to ensure quality of BGMs results at KNH.

1.1 PROBLEM STATEMENT

Use of BGMs in diabetes management has increased significantly globally because of increasing prevalence of diabetes mellitus.

It has been noted that errors in BGM user occur and can adversely affect patient care. Standards to ensure quality of POCT including BGM have been established globally, that lead to reduction in treatment related complications in diabetes, when implemented.

In Kenya, the prevalence of diabetes is also increasing and BGM use has been recommended. It is important to ensure that measures are taken to promote quality of BGM results for patient safety.

1.2 STUDY JUSTIFICATION

There is a tremendous increase in POCT and the global growth was estimated to be about 12% to 15% a year compared to the 6% to 7% growth rate of central laboratories (Wagar 2008). Financially the worldwide POCT market was projected to be close to $30 billion by 2018 (Kurec 2014). POCT for blood glucose takes the lion's share of the global multibillion-dollar market.

Although technology has significantly improved POCT quality, there are still many opportunities for errors to occur. In healthcare facilities, challenges to POCT quality arise from the multiple POCT sites, multiple testing devices and non-laboratory analysts, who may have little understanding of quality testing. Absence of clear guidelines for POCT and the immediate use of POCT results for patient care increase the error risk. Planning and management of the entire POCT system are essential to reduce errors and improve quality and patient safety (Ehmeyer 2011). Several western countries implement policy guidelines for POCT such as clinical and laboratory standards institute (CLSI) POCT 12-A3: 2013 (Rajendran and Rayman, 2014)

The national public health laboratory services in Kenya (NPHLS, 2016), indicated the need for guidelines to instruct non-laboratory personnel who perform most of the point of care tests on issues such as POC equipment performance, methodology of the test and quality of results obtained. At the KNH POC glucose is widely used, with each ward, specialized unit such as burns unit and outpatient (OP) clinic in KNH having a BGM. These tests are mainly done by nursing officers. It is not known whether the recommended quality assurance protocols are adhered to in these settings.

This study identified the measures that are currently in place to ensure the quality of POC glucose at the KNH as well as the gaps. The results of the study will form a baseline for establishing a framework and plan for quality assurance of POC glucose at the KNH to enhance safety of diabetic patients.

1.3 STUDY OBJECTIVES

1.3.1 BROAD OBJECTIVE

To evaluate the quality measures undertaken for POC glucose analysis at KNH and OP clinics.

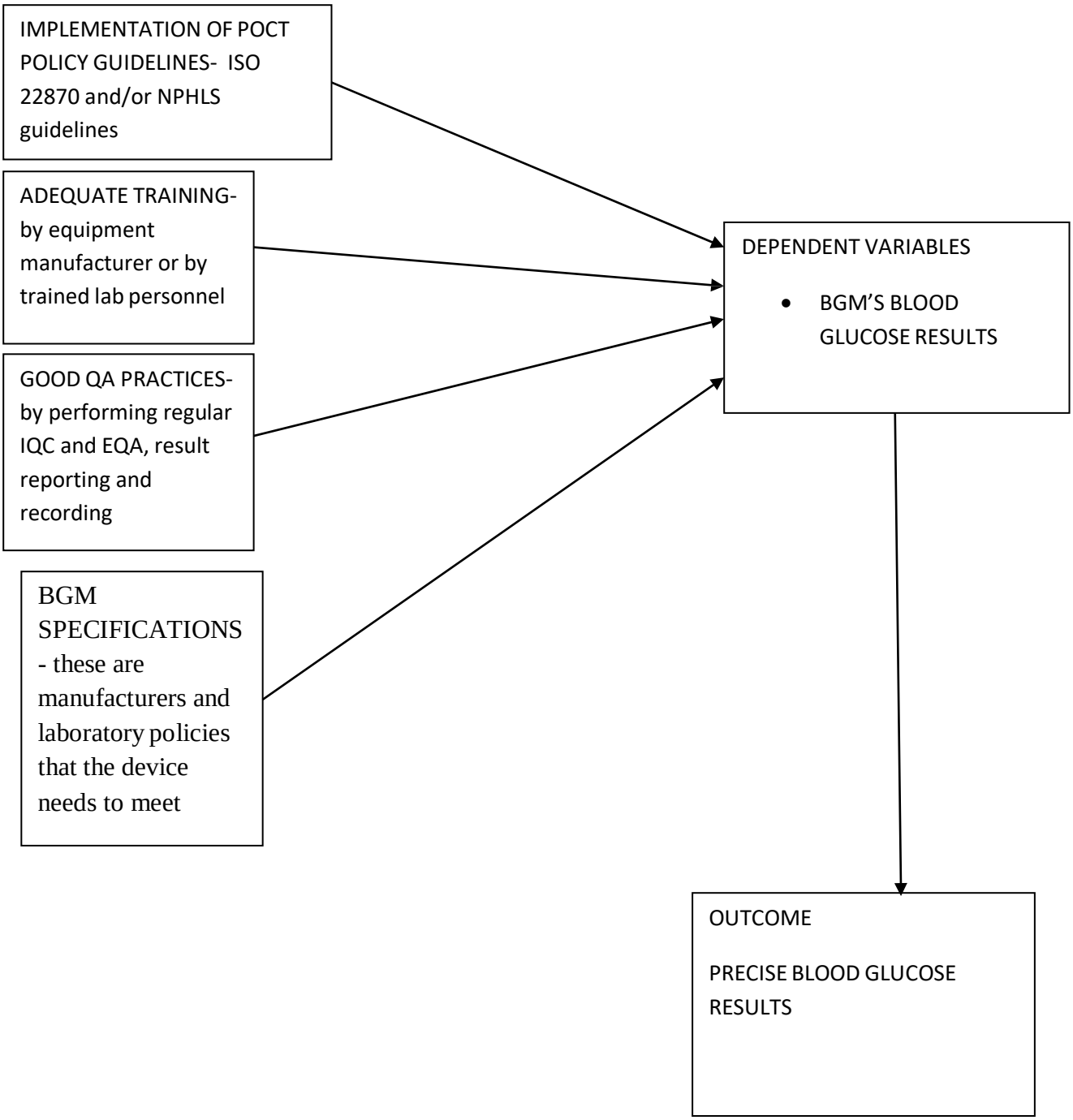
1.3.2 SPECIFIC OBJECTIVES

1. To describe the performance specifications of BGMs in use at KNH.
2. To identify policies/guidelines on POC glucose analysis at KNH.
3. To assess the training and competence of BGM users.
4. To evaluate QA practices in place at KNH for the use of BGMs.

1.4 STUDY QUESTION

What are the quality measures applied in POC glucose analysis at KNH?

1.5 CONCEPTUAL FRAMEWORK



CHAPTER TWO

2.0 LITERATURE REVIEW

2.1 INRODUCTION

For any point of care testing (POCT) program to be successful the users must undergo continuous training, competency has to be assessed regularly, validation of the analytical method and comparing the POCT results to a central laboratory method (Peterson JR et al., 2008; Mion MM et al., 2017).

In countries such as United States of America (USA) there are regulatory bodies such as the college of American pathologists (CAP), that require that all hospital POCT must be monitored by the hospital's central laboratory. This supervision covers all laboratory processes of the pre-analytical, analytical and post-analytical stages (Nichols JH, 2007).

In Kenya, the policy guideline, not yet implemented, describes an enactment plan that is meant to streamline POCT governance through the ministry of health (MOH), county health management programs and other organizations such as national AIDS STI control program (NASCOP) and others. The implementation of this guideline was to start in the first quarter of 2016, with roll out completed by the end of 2019. The funding would come from MOH and county governments through the support of development partners.

Kenya has implemented international organization for standardization (ISO) 22870:2006 for POCT facilities and ISO 15189 for medical laboratories for the accreditation of POCT services.

2.2 HISTORY OF BGMs

In 1965, the first glucose test strip was developed, it was called dexrostix. It was designed using a semi-permeable membrane which is embedded with red blood cells (RBCs) but permeated soluble glucose and there would be a glucose/peroxidase reaction (Free AH and Free HM,1964), gluconic acid then leads to the production of hydrogen peroxide, orthotolidine is oxidized to a deep blue chromogen by the hydrogen peroxide (Clarke and Foster, 2012)

Chemistrip bG and dextrostix invented around the same time, measured glucose qualitatively and were widely used in hospital settings. However, dextrostix was problematic in that there was no clear discernment of colours across different glucose levels (Cheeley and Joce, 1990)

These challenges, triggered the need to develop test strips that were automated thus improving precision, consequently giving more measurable blood glucose results (Clarke and Foster, 2012)

In the subsequent years after 1970, there emerged first generation blood glucose monitors (BGMs) which required washing and blotting to remove RBCs from the dextrostix strips and other modified reagent strips. (Brunton WA et al., 1977; Mendosa, 2006)

The second generation in 1987, used a small strip that contained the reagent, a small amount of blood was applied on it. The strip was already inserted in the meter and the results were displayed after 45 seconds (Leroux and Desjardine, 1985)

The third generation developed in the same year, 1987, used an enzyme electrode strip. The strip contained glucose oxidase and ferrocene (electron transfer agent), the reduced ferrocene was reoxidized at the electrode to generate a current detected by an amperometric sensor (Burrit MF, 1990)

Gradually, BGMs have become simpler to use and have technical developments such as auto calibration and detection of errors such as inadequate samples (Clarke and Foster, 2012)

2.3 POLICIES AND GUIDELINES IN PLACE FOR USE OF BGMs.

Monjelat et al., (2018) in the food and drug administration (FDA) summarized the clinical laboratory improvement amendments laws (CLIA) passed in 1988. The laws were to ensure all laboratories produce quality results.

FDA categorized the laboratory tests into 3 levels.

a. CLIA complexity- requires highly skilled personnel.
b. Moderate complexity tests- are semi-automated tests and require personnel to have some skills.
c. Waived tests- require little skills to operate and can be used by non-skilled personnel even for home use.

Dubois J. (2019) found out that, when a user utilizes a glucose meter in a manner not approved by the FDA, it is termed as off label.

a. BGMs become high complexity when they are used on patients in acute facilities for example intensive care unit (ICU) and emergency departments.
b. When a facility uses a BGM on a critically ill patient when the manufacturer is against the patient population a CLIA certificate of compliance (CoC) or certificate of accreditation (CoA).
c. Establish performance specifications such as accuracy, precision, sensitivity, specificity and other performance characteristics.

Policies are divided into two, manufacturer's policies and lab policies all put in place to improve the accuracy of BGMs.

Manufacturer's policies are different depending on the country/region. For Europe, European Norm (EN) international organization for standardization (ISO) 15197 (2015) defines a BGM to be accurate if ≥ 95% of results fall within ±15mg/dl (0.83mmol/L) of a laboratory result when blood glucose concentrations are < 100 mg/dl (5.56mmol/L) or within ±15% of the reference when the blood glucose concentrations are ≥ 100mg/dl (5.56mmol/L)

On the other hand, FDA guidance (2006) recommends that 95% of all BGMs results should be within ± 15% and 99% of all BGMs results should be within ± 20% of the reference laboratory method across the specified range.

Lab policies encompass managerial and technical requirements. The clinical and laboratory standard institute (CLSI) POCT 12-A3 (2013) in the United States of America (USA) is an example of a guideline. It is meant for BGM users in acute and chronic facilities where laboratory support is available. The document guides health care providers who manage diabetes mellitus (DM) patients and other conditions that lead to disruption of glycemic homeostasis. It recommends not screening or diagnosing DM using these devices. It also recommends that all device operators must be skilled and must perform quality assurance (QA) procedures. It also explains the quality management approach in setting up standards and guidelines for project management.

For an institution to be accredited for any POCT program it must conform to ISO 22870 which are requirements for standards of quality and competency of staff as the basis of establishing a formal quality management system (QMS); the institution also has to conform to ISO 15189, which specifies QMS requirements for medical laboratories.

2.4 TRAINING AND COMPETENCY ASSESSMENTS FOR BGM USERS

POCT is conducted by various clinical personnel that do not require skills possessed by technologists in the central lab. The technologists carry out many tests using few analyzers while POCT use a variety of devices in many locations (Gregory K et al., 2012; Mion MM et al., 2017)

Competency assessment is one method to ensure that POCT operators are skilled in the test procedure and in the reporting of test results (Khan AH et al., 2019).

CLIA' 88 requirements for competency assessment involve:

a. Direct observation of pre-analytical, analytical and post analytical stages.
b. Monitoring, recording and reporting of test results.
c. Review of test results, quality control (QC) and external quality assurance (EQA) records.

Shaw (2015) found out that, non-laboratory health care providers do not know the importance of QC and QA

In a study based on auditing of POCT results in a hospital, showed that 30% of the POCT glucose results were reported wrongly in the patient's record. It also showed that 12% of the results were not documented on the patient's record (Cerraro and Plebani, 2009)

One of the most common errors in BGM use is failure to calibrate the machine. Recalibration of the meter is necessary every time a new batch of glucose strips is opened and at least once a month. The calibration solutions are provided by most manufacturers. Perfection is unattainable in getting accurate results but it is important to be as accurate as possible, hence excellent technique and training is essential because it is undervalued (Hellman R, 2012).

2.5 QUALITY ASSUARANCE OF BGMs

(FDA, 2019) found out that the accuracy of the glucometer blood test depends on

a. The quality of the glucose meter and test strip
b. Handwashing technique
c. Hematocrit levels of the patient.
d. Interfering substances that affect meter results usually indicated by the manufacturer.
e. How the user follows the manufacturer's instructions on how to handle the meter and storing of the glucose strips.

In addition (FDA, 2019) has guidelines to make sure that the glucometer works properly

1. Use liquid control solutions when a new batch of strips is opened or regularly as strips are being used from the same batch.
2. Use electronic checks. If it detects a problem it will give an error code (the manufacturer has instructions on how to solve the codes).
3. Compare the glucometer test result with a blood glucose test with a central laboratory test for example the hexokinase method. If the two results tally, it shows that the meter is accurate and the user has good technique.

According to Khan et al., (2019) some of the QA practices that could improve POC testing include:

a. Carrying out IQC and EQA regularly.
b. Carrying out regular assessments and audits
c. Standard operating procedures (SOPs) implementation for each test
d. Result reporting and recording.
e. Reporting performance of unusual results and occurrence management.
f. Regular equipment maintenance.
g. Implementation of safety and infection control measures.

2.6 ERRORS IN BGMs

Although it has been half a decade later, since the invention of the first BGM there are significant problems associated with their use, despite constant improvements in the devices. For instance the difference of glucose values using different BGMs may be as much as 2.78-3.89 mmol/L (Dungan K et al., 2007)

Both total and analytical error affects the working of BGMs (Krower and Cembrowski, 2010)

Pre-analytical errors that affect BGMs performance include exposure of strips to extreme temperatures either high or low, strips exposed to humidity or dirt, uncalibrated machines, lack of handwashing before the procedure, using wet hands during the procedure and using the wrong amount of sample on the strip (Hellman R, 2012)

Analytical errors include improper calibration and inadequate maintenance (Richard J et al., 2007)

Post analytical errors include misreading of glucose results either via over estimating or underestimating (Clarke and Foster, 2012)

Total allowable error in the USA, FDA standard requires a meter's performance to be within ±20% of a blood glucose reference standard for 95% of the glucose values $\geq$ 5.56mmol/L and an allowable error $\leq$ 0.67 mmol/L for 95% of the glucose values < 5.56mmol/L this means that for

a reference blood glucose value of 5.56 mmol/L, the glucometer's reading should be between 4.44mmol/L-6.67mmol/L)

2.7 INTERFERENCES OF BGMs

Almost all BGMs give false hypoglycemic states in conditions such as diabetes ketoacidosis (DKA), poor tissue perfusion conditions and hyperosmolar states (Dungan K, 2007; Tonyushkina and Nichols, 2009)

Blank et al., (2009) also found out that, in the presence of DKA, BGMs can underestimate the true glucose values as much as 16.67 mmol/L

Both BGMs using glucose oxidase or glucose dehydrogenase are readily affected by interfering conditions such as anemia, polycethemia, hypoxia, hypotension, DKA, severe acidosis (Hellman R., 2012).

Patient's state that affect BGM results include levels of hematocrit, if the patient is hypoxic, severely hypoglycemic or hyperglycemic, has a low systolic blood pressure, has increased triglycerides levels and uses some drugs such as vitamin C. (Sacks D et al., 2002; Saudek and Kalyani, 2006).

CHAPTER THREE

3.0 METHODOLOGY

3.1 STUDY DESIGN

Mixed methods- Descriptive cross sectional and qualitative phenomenological study designs. Descriptive cross sectional study included analysis of QC material and administering questionnaires, containing open and closed ended questions, to the nurses performing the procedure. Qualitative phenomenological study included conducting interviews from experts these were, the nurse managers. The study obtained their expert opinions on certain aspects of glucose testing.

3.2 STUDY AREA

The study was conducted at KNH. KNH is a public, teaching and teaching hospital. It has a bed capacity of 1800. It is located on hospital road, Nairobi. The hospital is 3.5km from the central business district.

3.3 STUDY POPULATION

BGM users in the wards on levels 1,3,4,5,6,7,8,9,10, labour ward, GFA, newborn unit (NBU), neonatal intensive care unit (NICU), burns unit, CCUs on the 7^{th} and 8^{th} floor and renal ward; this made up 44 study sites. The BGM users were mostly nurses and there were approximately 10-30 nursing officers in each one of these areas.

Nurse managers- There were 2 nurse managers in each area. There was the senior and an assistant manager.

3.4 INCLUSION CRITERIA

1. All nurses/BGM users who gave consent.
2. All nurse managers who gave consent.

3.5 SAMPLE SIZE

3.5.1 SAMPLE SIZE DETERMINATION

a) Cross-sectional study:

The Cochran's formula (Cochran 1977) was used to calculate the number of nurses to be used in this study as follows:

A study done in Germany by Bietenbeck et al (2018) found that 79% of EQA participants for POCT glucose achieved good performance.

$$N = \frac{Z^2pq}{d^2}$$

Where N= sample size

z=normal deviation at the desired confidence level (95%)

p=79% i.e. 0.79

q=1-0.79=0.21,

d= 0.05, the degree of precision, which is 5% with a confidence interval of 95%

Therefore:

$$\frac{(1.96)^2(0.79)\ (0.21)}{(0.05)^2}$$

=255 nurses

Since the target population is less than 10000 then the formula is modified to

N_f=N+N/1+n (Mugenda.O.M and Mugenda A.G, 1999)

N_f= Desired sample size for population of <10,000

N= Desired sample size when population is >10000

n=Estimate of population size

Therefore;255/ (255/2000)+1

N_f=226 nurses

The sample was distributed equally in all the areas where BGMs were used at the Kenyatta National Hospital, which were 44 sites, therefore 5 nurses were enrolled from each study area

(226/44 =5). However during the study after sampling the 44 sites we did not achieve the sample population of 226 nurses, therefore GFB (Post-natal ward) and Paediatric intensive care unit (PICU) were included in the study raising the sample size to 230 and the sample sites were increased to 46 sites.

b. Qualitative study:

For this component, twelve (12) Nurse Managers were selected. For phenomenological studies, it is reported that data is usually saturated when a researcher samples from 5-25 participants (Creswell, 1988).

3.6 SAMPLING METHOD

a) For the cross-sectional study, participants were selected via convenience sampling. In each study site, the nurses on duty at the time were approached and invited to enroll into the study, if they met the inclusion criteria. This was done consecutively till five nurses were enrolled at each site.

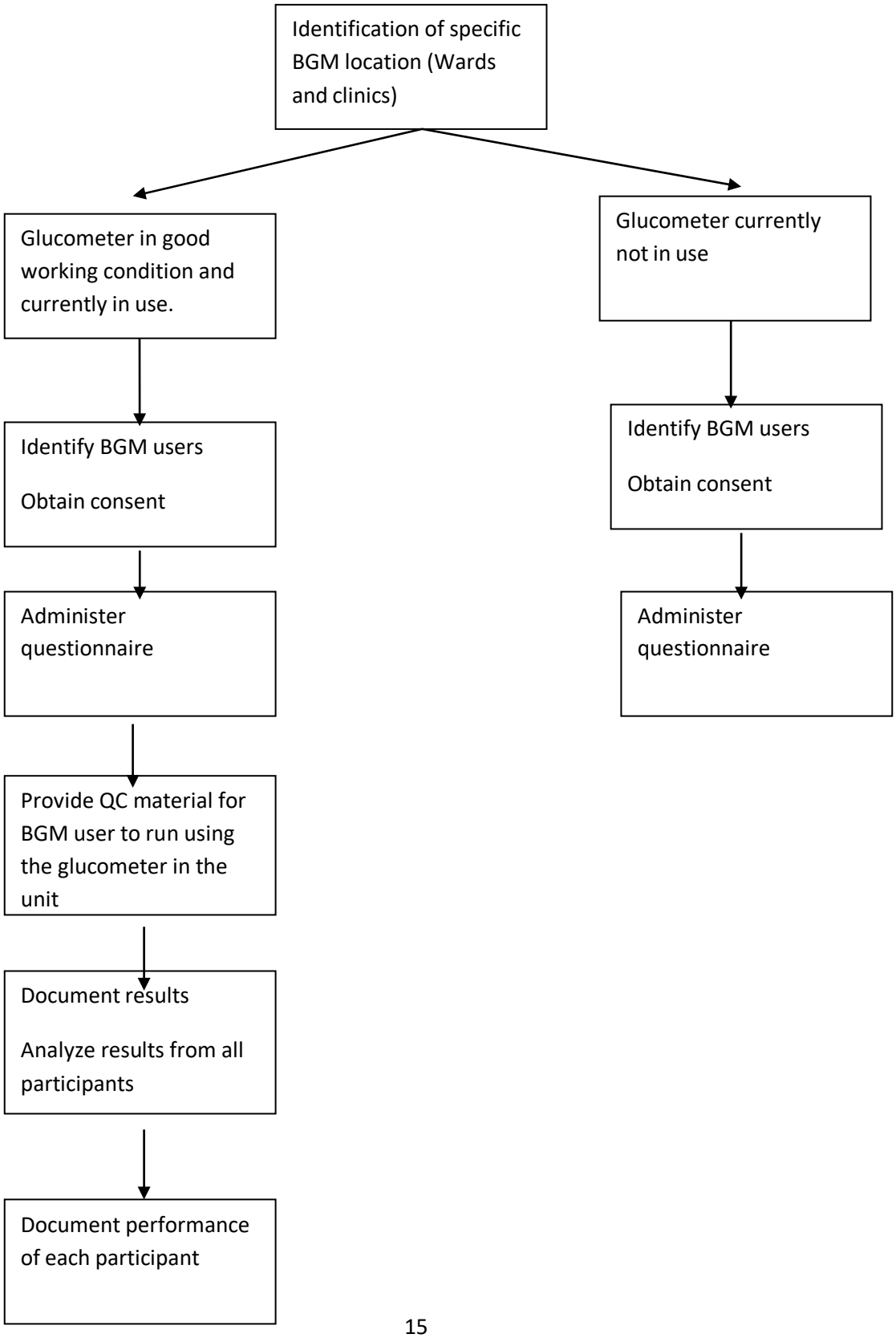
b) Qualitative study: Nurse Managers were selected by convenience sampling. The Nurse Manager on duty at the study site was approached and invited to participate in the study. This was done in each site until the sample size was achieved.

3.6.1 DATA COLLECTION PROCEDURES

a) For the cross-sectional study, after administering consent, the study participants were requested to fill the study questionnaire. If the glucose POCD at the site was functional, the lottery method was used to select one (1) nurse out of the five, to perform glucose analysis on the POCD in the unit, using a QC sample, which the researcher provided. Results of the glucose analysis were documented in the data collection sheet.

If however, the glucose POCD was not functional at the site, the researcher obtained the data from the questionnaires. The flow of data collection is shown in the work plan (3.6.2) below.

3.6.2 WORKFLOW PLAN FOR QUANTITATIVE DATA COLLECTION PROCESS



b) For the qualitative study, after the nurse manager gave consent, data was collected using a phenomenological tool which contained questions that required the participant's view or opinion about point of care glucose testing. The researcher sought permission from the participant to use a tape recorder during the interview. The recorder was secured to safeguard the information

3.6.3 PRETESTING OF THE QUESTIONNAIRE

The researcher used 4 (10% of the population) clinics from KNH to pretest the data collection tool. These were the surgical, medical, reproductive clinics and Comprehensive Care Centre (CCC). One nursing officer from each of these clinics was randomly selected. They were requested to fill the questionnaires after an informed consent was obtained. These nurses were not eligible to participate in the study. Questionnaire results were analyzed to establish whether they accomplished the study's objectives. Ambiguous questions identified were corrected. The questionnaire was accepted because more than 70% of the questions were answered as expected. (α coefficient was greater than 0.7)

3.7 QUALITY ASSURANCE

Pretesting of the questionnaire enhanced quality of the data collection. For the glucose testing, the commercial QC material was obtained but was in liquid form and did not need to be reconstituted. The blood glucose machine used to assign glucose values was from KNH central biochemistry laboratory (lab 16). There was strict adherence to good laboratory practice (GLP) and standard operating procedures to minimize the errors in the pre-analytical, analytical and post-analytical stages.

3.7.1 ETHICAL CONSIDERATIONS

Permission and clearance were sought from UON and KNH research and ethics committee.

Ethical research principles were adhered to. The researcher fully described the nature of the study, the participant's right to decline participation, the researcher's responsibility and likely risks and benefits so that the participant could make an informed voluntary decision about their participation in the study. Participants were explained to that their participation or information that they provided was not to be used against them in any way. The participants provided written consent

Participants had the right to decide at any point to withdraw their participation and to refuse to give information or to ask for clarifications.

Confidentiality was maintained in data collection, analysis and storage. Data was secured under lock and key only the researcher had access to it.

The results of the QC analysis were disseminated for the study site nursing staff, for purposes of quality improvement. The unique site number was used in this dissemination to maintain the confidentiality.

Standard measures were implemented to protect the researchers and the study participants from COVID-19 during the study.

3.8 DATA MANAGEMENT AND STATISTICAL ANALYSIS

Quantitative data

After collection, the data was first organized, the questionnaires which were incomplete or had vague answers were set aside.

Data were presented in tables, bar graphs and pie charts

For the QC analysis, the mean, standard deviation (SD) and coefficient of variation (CV) of the glucose values obtained from the study sites were calculated. These were referred to as the consensus values and were compared to the assigned values generated by the researcher. The results obtained from each study site were also compared with the consensus mean as well as the assigned values for the two levels of QC materials. Individual participant results were assessed as acceptable when glucose concentration obtained were within ± 3 SD of the consensus mean or the assigned value. Participant glucose values that exceeded ± 3 SD of the consensus mean or the assigned values were labeled as unacceptable.

The distribution of the participant values was presented using line graphs.

Qualitative data

The data were transcribed, translated and presented in themes by the researcher.

CHAPTER FOUR

4.0 RESULTS

This study used a mix method study design where two hundred and forty-two participants were randomly selected from wards and special units; where POC blood glucose testing was done at the KNH. The study participants included nurse's performing POC blood glucose tests, as well as nurse managers of the wards and clinics. Qualitative data was collected from the nurse managers in respective wards and special units. Of the total respondents, two hundred and thirty participated in quantitative data collection method while twelve responded to the qualitative phenomenological tool.

4.1 Quantitative results for questionnaires

4.1.1 Demographic Data

For the quantitative arm of the study, data two hundred and thirty responses qualified for analysis. Of the total respondents 47.0% (*n*=108) were aged between 20-30 years and only 7 respondents (3%) were above 50 years of age. On the years of experience in the ward/clinic, most of the respondents (50.4%) had 1-5 years' experience, and only 5.2% (*n*=12) had less than one year experience. This is shown in Table 1 below.

Table 1: Demographic data and work experience of study participants

Variables	**Frequency n=230**	**Percentage (%)**
Age		
20-30 years	108	47.0
31-40 years	85	37.0
41-50 years	27	11.7
>50 years	7	3.0
No response	3	1.3
Gender		
Male	66	28.7
Female	159	69.1
No response	5	2.2
Years worked in the ward/clinic		

<1 year	12	5.2
1-5 years	116	50.4
6-10 years	62	27.0
>10 years	35	15.2
No response	5	2.2

4.1.2 General information on glucometers

This data was collected from all the wards and special units the data collected was evenly distributed with each ward representing a 2.2% of the sampled data.

During the time of this study, KNH had at least 306 glucometers of which 277 were functioning (Figure 1). Most of the respondents (70.4%) indicated that there was only one (1) glucose meter in the ward/clinic. About a quarter of the respondents (24.8%) indicated that their ward/special unit had 2 glucose meters

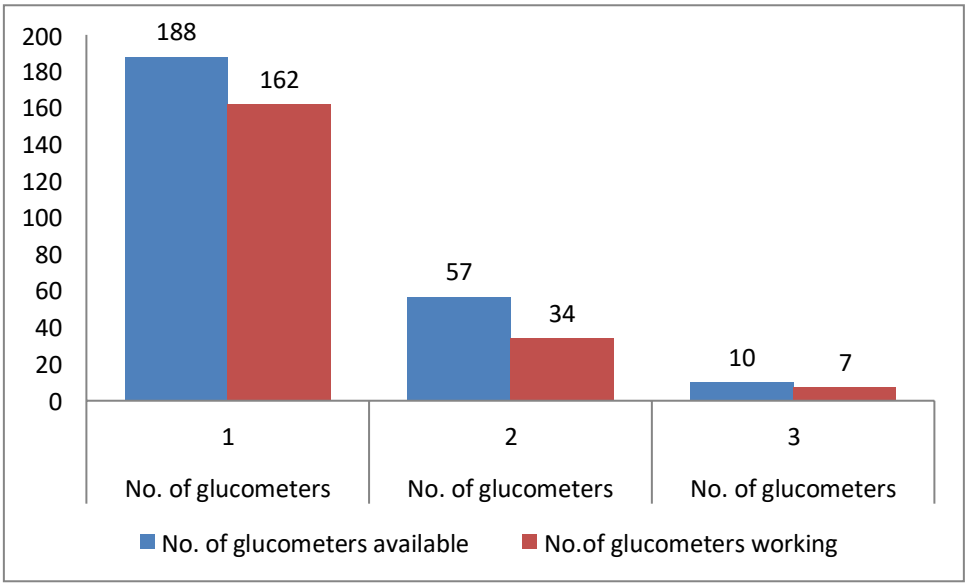


Figure 1: Number of Glucometers Available and Working at KNH

Most of the glucose meters (67.4%) had been operational for less than a year. The study found that six (5) different types of glucose meters were being used in the wards and special units. The

Caresens glucometer was most widely used by more than two third (67.8%) of the respondents followed by Sinocare meters by 13% of the respondents. This is as shown in Table 2 below.

Table 2: General information on glucometer used at KNH

Variables	Frequency n=230	Percentage (%)
Period the working glucometer has been in use in the ward/clinic		
<1 year	155	67.4
1-2 years	27	11.7
Don't know	39	17.0
No response	9	3.9
Name of glucometer used		
Accucheck	11	4.8
Caresens	156	67.8
Glucheck	1	0.4
Oncall plus	1	0.4
Sinocare/Safe care	33	14.3
Don't know	10	4.3
No response	18	7.8

4.1.3 Quality management systems (QMS)

4.1.3.1 Information on quality management system

When asked about quality management, most of the respondents (61.7%), respondents had come across the ISO 9001:2015 quality management standard but only 16.1% had ever heard of ISO 22870 and ISO 15189 laboratory quality management standards. More than a third of the respondents (40%) indicated that they had a Standard Operating Procedure (SOP), guiding glucose testing using a glucometer. Regarding the glucometer's inserts, majority of the respondents (77.4%) had seen the inserts but only 58.3% indicated they had ever read it. This is shown in Table 3 below.

Table 3: Quality management standards and standard operating procedures for glucose testing using glucometers

	Frequency n=230	**Percentage (%)**
Have you ever come across the ISO 9001:2015 Standard?		
Yes	142	61.7
No	84	36.5
No response	4	1.7
Have you heard about the ISO 22870 and ISO 15189 Standards?		
Yes	37	16.1
No	190	82.6
No response	3	1.3
Is there a policy document indicating responsibility or accountability of glucose testing?		
Yes	84	36.5
No	141	61.3
No response	5	2.2
Do you have a Standard Operating Procedure (SOP), guiding glucose testing using a glucometer?		
Yes	92	40
No	134	58.3
No response	4	1.7
Is the SOP readily available in the ward/clinic?		
Yes	78	33.9
No	148	64.3
No response	4	1.7
Have you ever seen an insert for a glucometer?		
Yes	178	77.4

No	49	21.3
No response	3	1.3
Have you ever read a glucometer's insert?		
Yes	134	58.3
No	94	40.9
No response	2	0.9

4.1.3.2 Knowledge of quality assurance terminologies

Most of the study respondents (>66.7% , n=>154) indicating they have ever heard of the terms. The least quality assurance terms were IQC and EQA with less than a third <33.3% (<n=76) of the respondents ever heard of them.

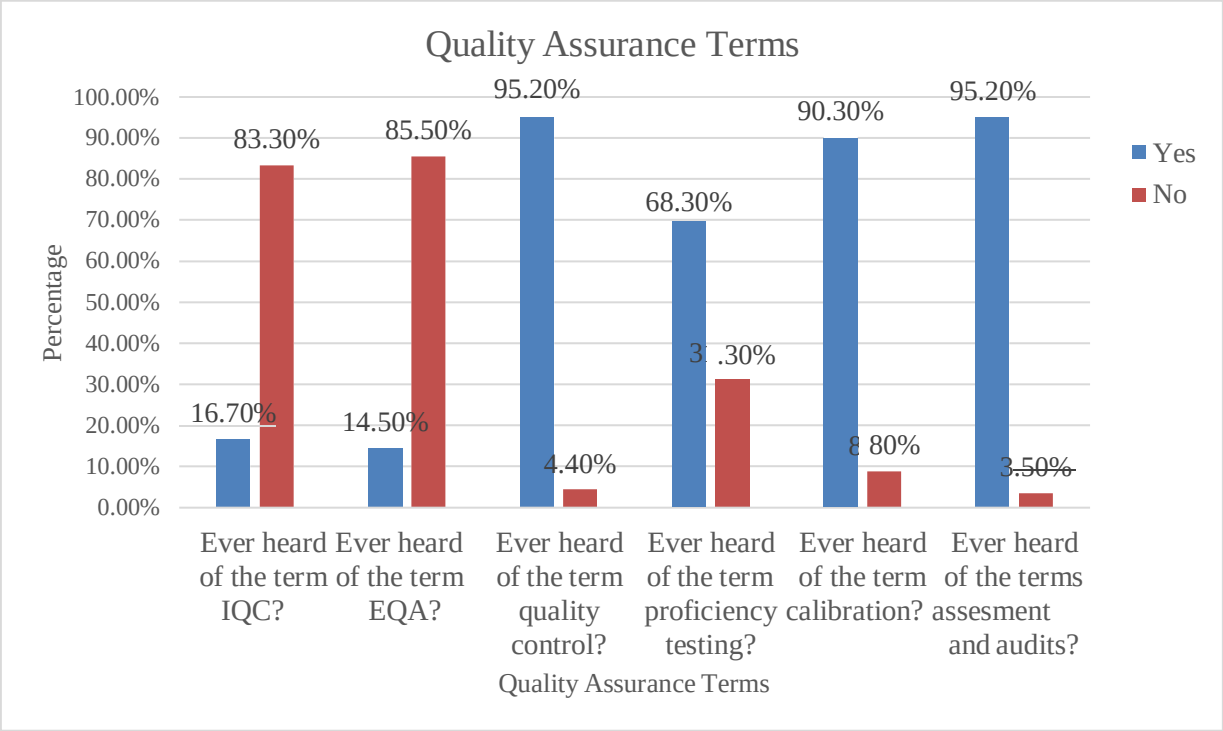


Figure 2: Knowledge of quality assurance terms

4.1.4 Safety Measures While Conducting Glucose Test.

4.1.4.1 Use of personal protective equipment (PPE)

On safety measures, the study found that majority of the respondents (64.2%) always used personal protective equipment (PPE) while carrying out glucose test using a glucometer, and five respondents (2.2%) indicated they had never used PPE while performing glucose testing. This is shown in Figure 2.2 below.

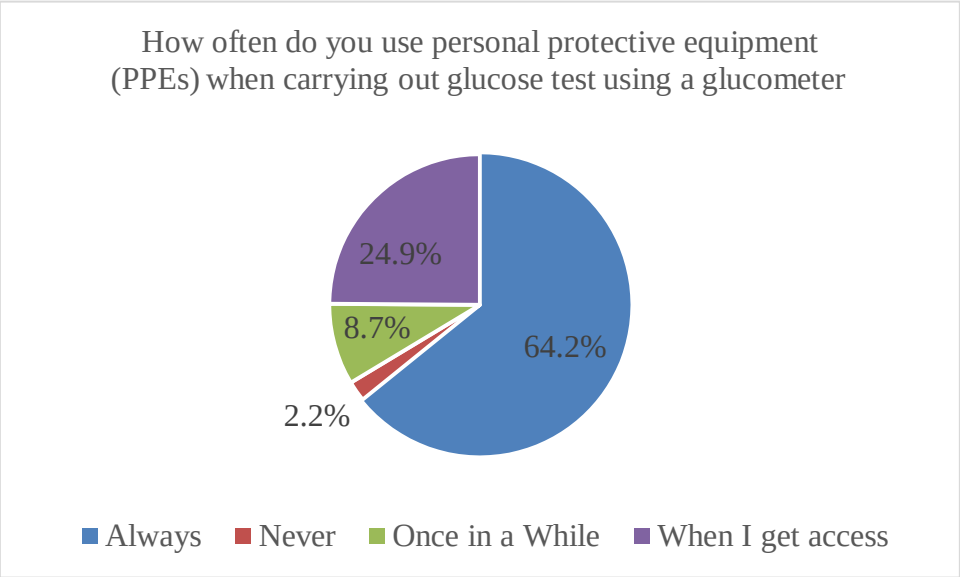


Figure 3: Use of personal protective equipment while carrying out glucose testing using glucometer

4.1.4.2 Other safety measures during glucose testing

The study showed that a sharps box was always readily available when health care providers were doing a glucose test (99.1%). On further exploration, 6.5% of health care providers reported having ever pricked themselves while undertaking the glucose test using glucometer. Most of the respondents (73%) reported that the glucose meters were accessible to all staffs in the ward/clinic including students, and almost all of them indicated there was a designated storage area for the glucose meters. This is as shown in Table 5.

Table 4: Safety Measures While Conducting Glucose Test at KNH

Variables	Frequency n=230	Percentage (%)
Is there a sharp box readily available when you are doing an actual test?		
Yes	228	99.1
No	1	0.4
No response	1	0.4
Have you ever pricked yourself when undertaking a glucose test using a glucometer?		
Yes	15	6.5
No	214	93.0
No response	1	0.4
Who has access to the glucometer?		
Everyone including students	168	73.0
Nurses only	24	10.4
Nurses and doctors	37	16.1
No response	1	0.4
Do you have any area designated for the storage of the glucometer?		
Yes	222	96.8
No	5	2.2
No response	3	1.3

4.1.5 Documentation of blood glucose results

Most of respondents (85%) indicated that glucometer results are documented in a special document in the wards. About half of the study respondent (52.6%) had experienced instances where they could not read the results from the display of the device clearly. Majority (75.2%) however reported that there was no document to report the unusual glucometer findings. Almost all respondents (98.3%) indicated they used the glucometer to measure blood glucose on critically ill patients as shown in Table 6

Table 5: Documentation and QA practices

Variables	**Frequency n=230**	**Percentage (%)**
Are glucometer's results documented in a special document?		
Yes	196	85.2
No	29	12.6
No response	5	2.2
Are there instances where you could not read the results clearly from the display of the device, for example could not tell whether a result is 8.0 or 5.0 mmol/l		
Yes	121	52.6
No	106	46.1
No response	3	1.3
If unusual results are obtained, is there a document to report these findings?		
Yes	52	22.6
No	173	75.2
No response	5	2.2
Have you ever used the glucometer device on a critically ill patient?		
Yes	226	98.3
No	1	0.4

No response	3	1.3

4.1.6 Maintenance of glucometers

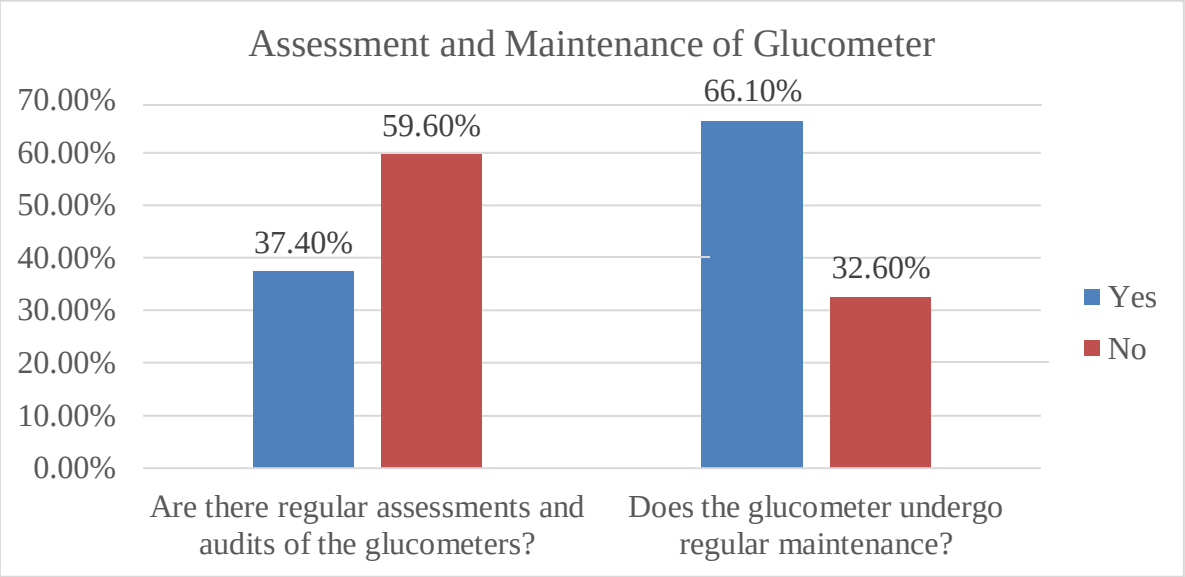


Figure 3: Assessment and Maintenance of Glucometers at KNH

4.1.7 Training on use for glucometers

4.1.7.1 Proportion of participants who had been trained.

Only 43.0% (*n*=99) of the respondents had been trained on how to use glucometer at KNH as shown in figure 5.

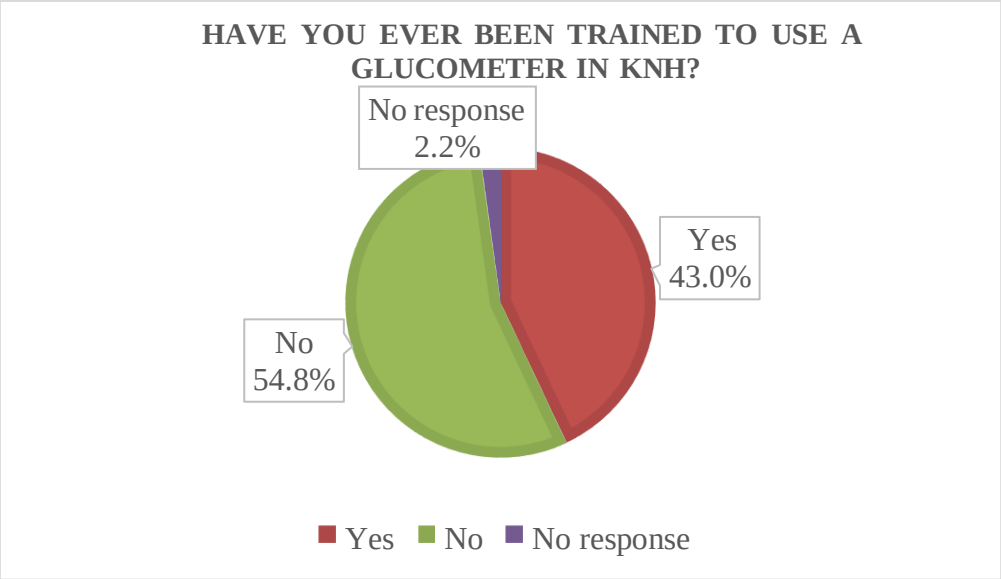


Figure 4: Training on how to use glucometer at KNH

4.1.7.2 Trainers for Glucometer use training

This study found that training was mainly done by glucometer supplier 35.4% (n= 81), followed by colleagues in the unit 24.2% (n=57). This is shown in Figure 6.

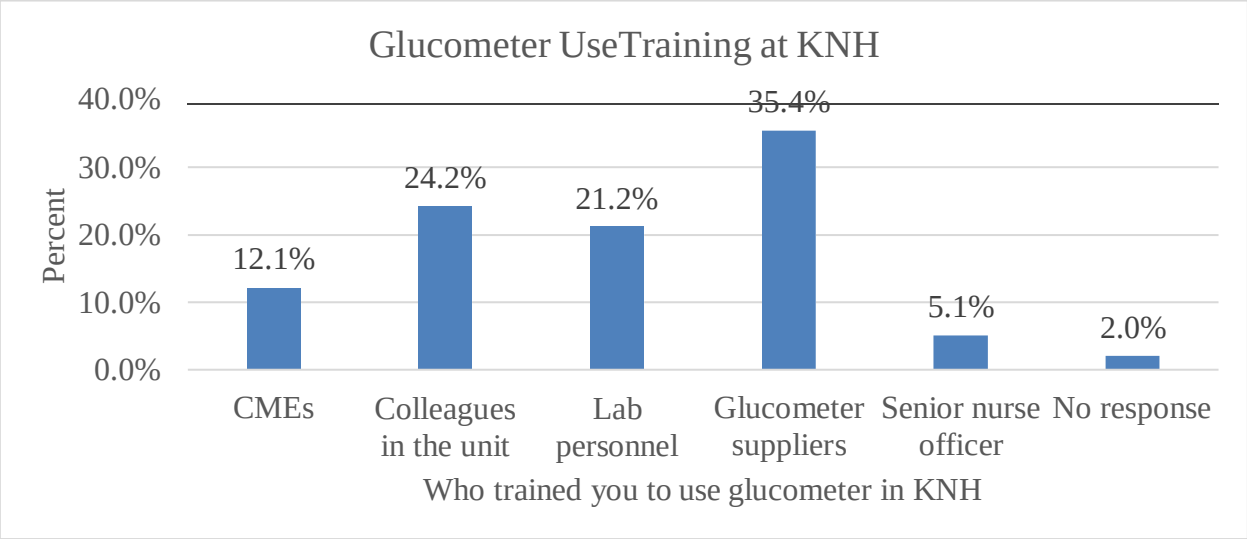


Figure 5: Glucometer use training at KNH

4.1.7.3 Assessment of Glucometer use training.

In this study, only 6.1% of the respondents had undergone competency assessment to examine their skills for POCT glucometer use and almost all respondents (94.3%) did not have certificates of competency. It was also established that nursing manual was available to 69.1% of health care workers in the ward/clinic KNH with 68.7% indicating that there were instructions on how to perform glucose analysis using a glucometer in the manual as shown in Table 7.

Table 6: Glucometer glucose test training assessment

Variables	Frequency n=230	Percentage (%)
Have you ever undergone competency assessment to measure your skills for POCT glucometer use?		
Yes	14	6.1
No	210	91.3
Have you received a certificate to show that you can operate a glucometer?		
Yes	6	2.6
No	217	94.3
No response	7	3.0
Is there a nursing manual available in the ward/clinic?		
Yes	159	69.1
No	67	29.1
No response	4	1.7
Are there instructions on how to perform glucose analysis using a glucometer in the nursing manual?		
Yes	158	68.7
No	65	28.3
I do not know	1	0.4
No response	6	2.6

4.2 Analysis of Quality Control results

A total of forty-sixresults were obtained from study participants who analyzed glucose control samples in the wards at the KNH using forty-six point of care glucose devises. Two (2) glucose control samples were used, one having a low glucose concentration and the other with a high glucose concentration.Control charts were used to examine the acceptability of the results.

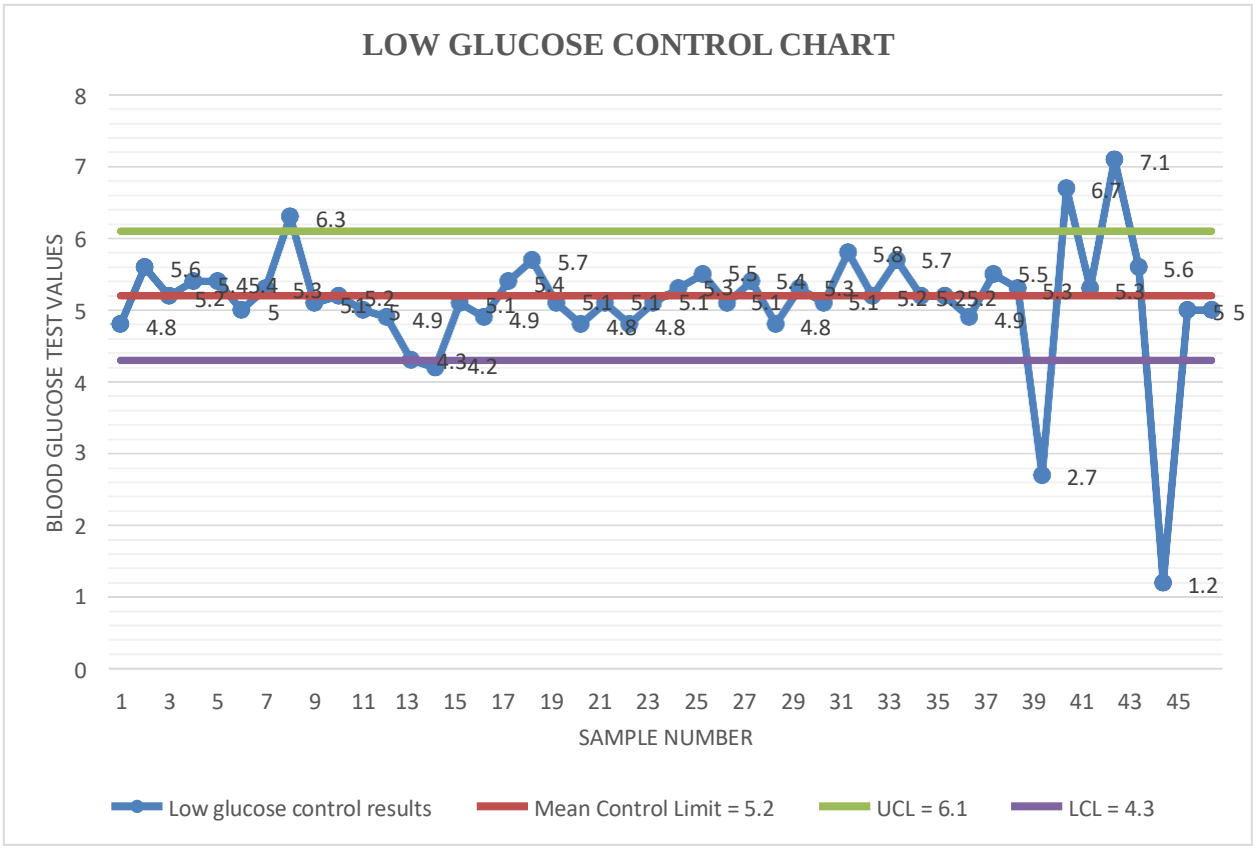
4.2.1 Low blood glucose control values

Acceptable values for the low blood glucose control were determined using the control mean and standard deviation as shown below.

Mean control value = 5.2mmol/L

Control standard deviation (*SD*) = 0.3

Lower Control Limit =(mean - 3*SD)	**Upper Control Limit =(mean + 3*SD)**
4.3mmol/L	6.1mmol/L



Acceptable blood glucose results are those within mean control value ± 3 SD. For the Low glucose control the acceptable values are those from 4.3 mmol/L to 6.1 mmol/L. Most of the study participants (87.0%) obtained blood glucose test results within this range. Only six participants (13.0%) obtained blood glucose test results outside the acceptable limits. The glucose results that were above the upper control limit of 6.1 mmol/L were 6.3mmol/L, 6.7mmol/L, and 7.1mmol/L, while the one that were below the lower control limit of 4.3mmol/L were 4.2mmol/L, 2.7mmol/L and 1.2mmol/L.

Blood glucose test results within mean control value ± 2 SD were 84.8% and those within the mean control value ± 1SD were 65.2%.

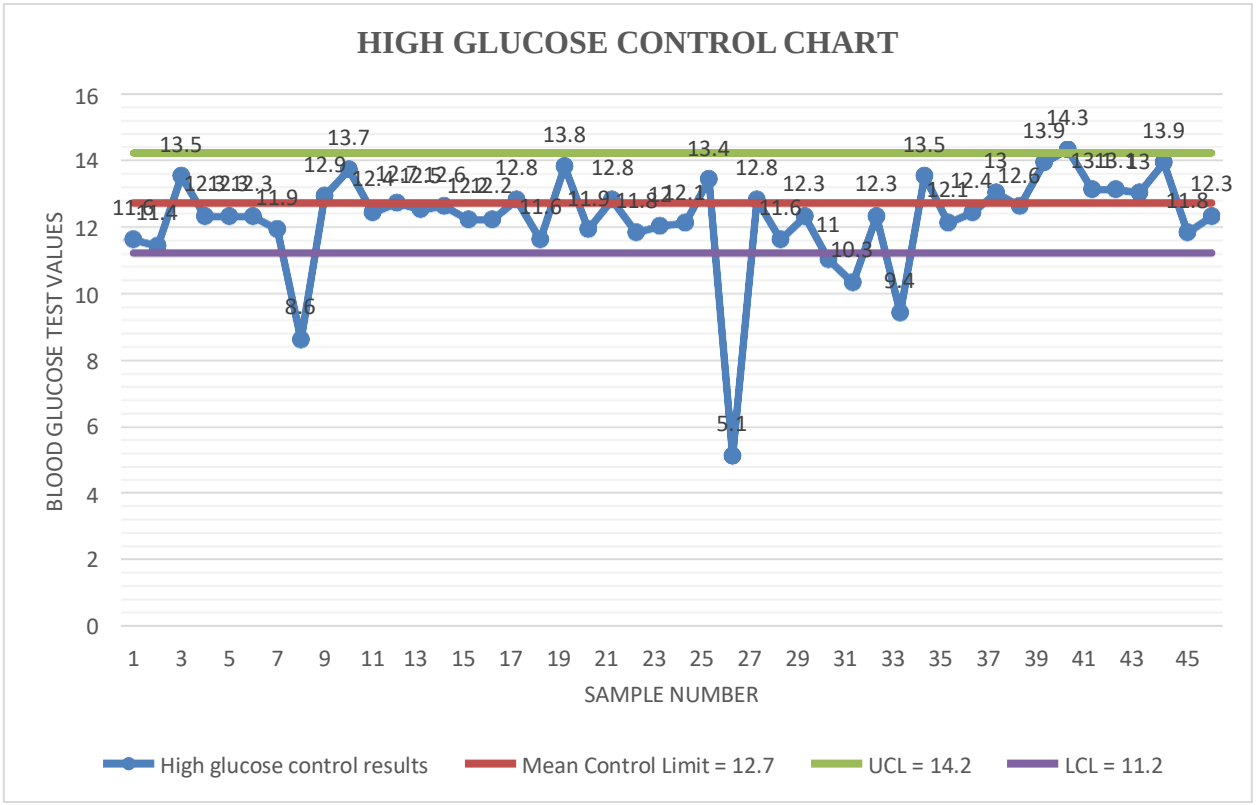
4.2.2 High blood glucose control values

Acceptable values for the high blood glucose control were determined using the control mean and standard deviation as shown below.

Mean control value = 12.7mmol/L

Control standard deviation (*SD*) = 0.5

Lower Control Limit =(mean - 3*SD)	**Upper Control Limit =(mean + 3*SD)**
11.2mmol/L	14.2mmol/L



The acceptable results for the high glucose control samples are those ranging from 11.2 mmol/L to 14.2 mmol/L. Most of the study participants (87%) obtained glucose results within the acceptable limits and many (47.8%) were within 1SD of the mean glucose value. Only one result was beyond the 3SD upper limit with 14.3mmol/L (sample number 41), while five results (10.9%) were below the 3SD lower limit (8.6mmol/L, 5.1mmol/L, 11.0mmol/L, 10.3mmol/L, and 9.4mmol/L).

4.2.3 Analysis using Consensus mean and standard deviation)

The study participants glucose results were also compared with consensus mean and standard deviation derived from all the study participants results after exclusion of outliers.

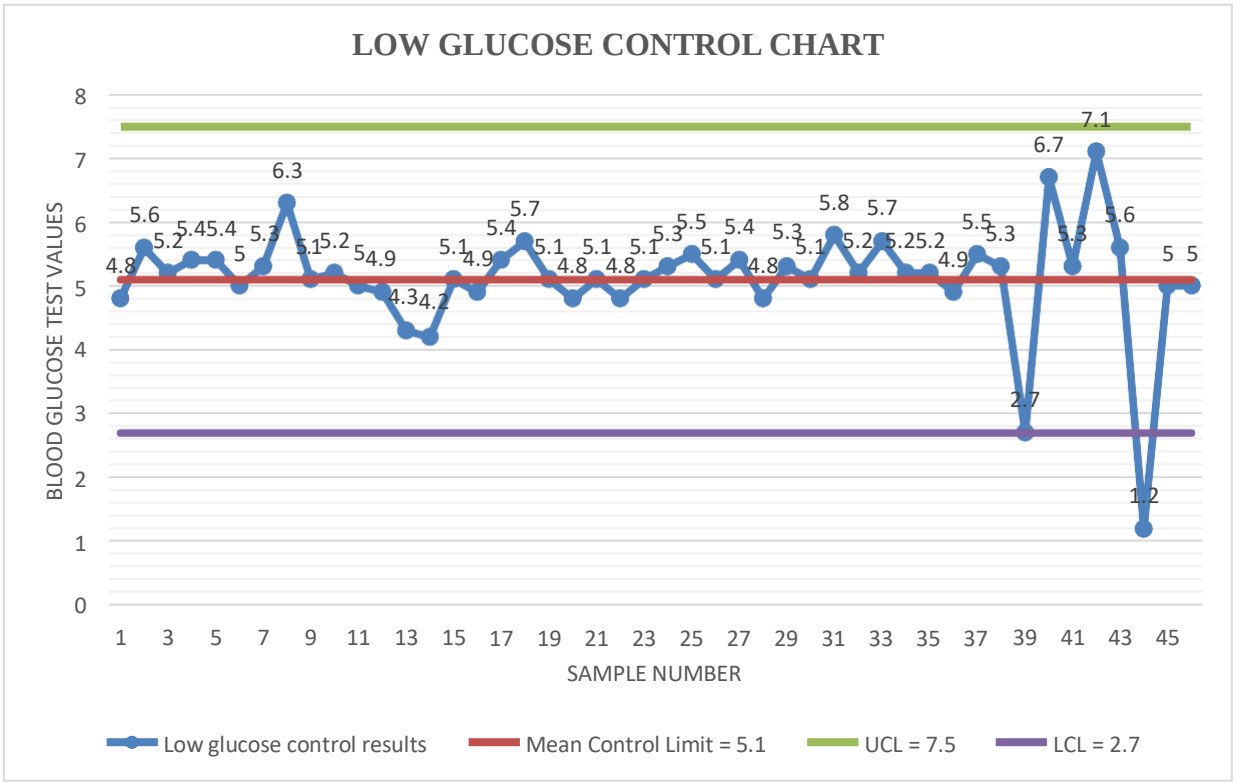
4.2.3.1 Low blood glucose control values (using Consensus mean and standard deviation)

Acceptable values for the high blood glucose control were determined using the consensus mean and standard deviation as shown below.

Mean control value= 5.1mmol/L

Standard Deviation (*SD*) = 0.8mmol/L

Lower Control Limit =(mean - 3*SD)	**Upper Control Limit =(mean + 3*SD)**
2.7mmol/L	7.5mmol/L



For the lower control chart with the consensus mean of 5.1 and *SD* =0.8, acceptable blood glucose results are those from 2.7mmol/L to 7.5mmol/L. Majority of the blood glucosetest

results (97.8%) were within 3SD of the mean glucose value, 93.5% were within 2SD and 87% were within the 1SD range. Only one test result was outside the acceptable limits of 3SD. There was no glucose result above the upper control limit of 7.5mmol/L.

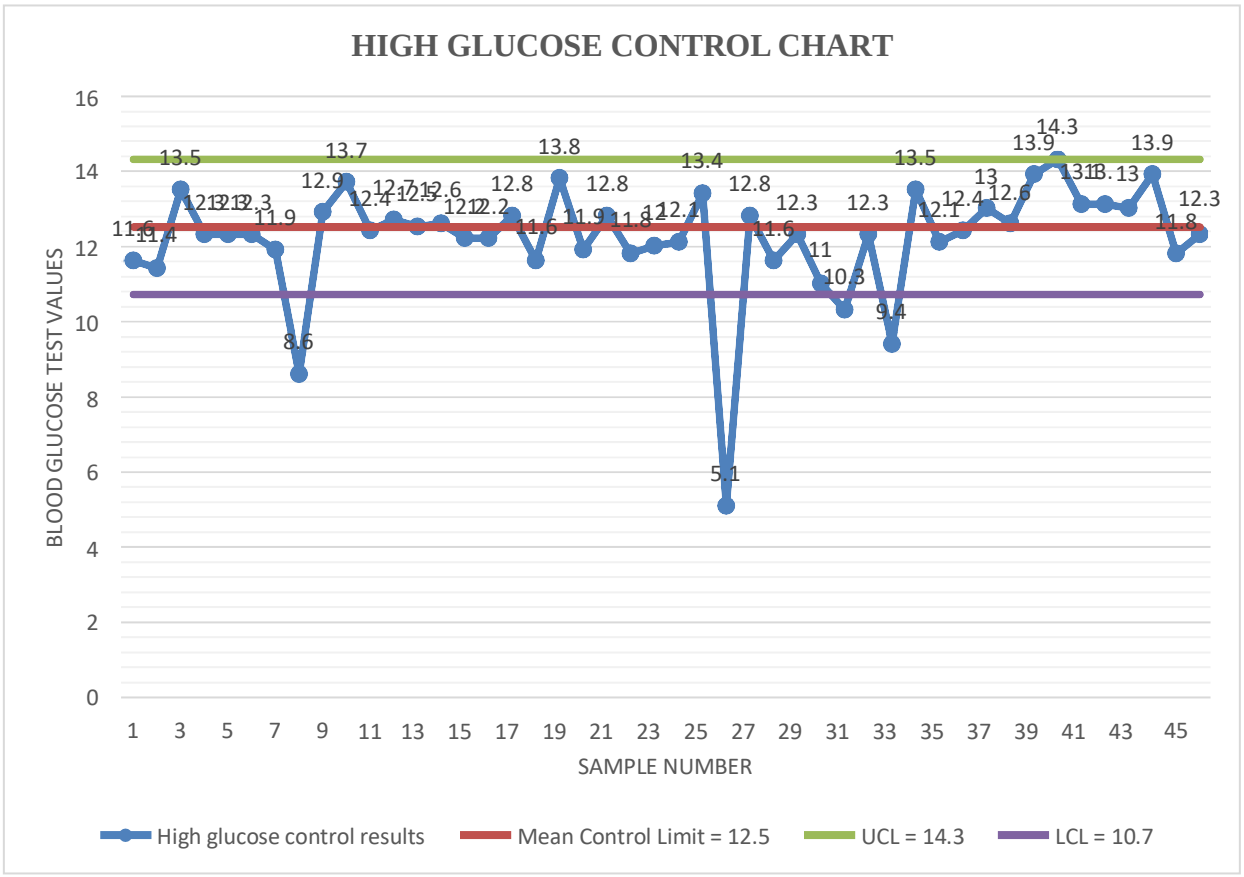
4.2.3.2 High blood glucose control values (using Consensus mean and standard deviation)

Acceptable values for the high blood glucose control were determined using the consensus mean and standard deviation as shown below.

Mean control value= 12.5mmol/L

Standard deviation (*SD*) = 0.6mmol/L

Lower Control Limit =(mean - 3*SD)	**Upper Control Limit =(mean + 3*SD)**
10.7mmol/L	14.3mmol/L



The higher control chart with the consensus mean of 12.5 and *SD* =0.6 shows that 91.3% of the blood glucose test results were within acceptable blood glucose results (from 10.7mmol/L to 14.3mmol/L).

4.2.4 Comparison of results Sinocare and Caresens glucometers

The study compared the Sinocare and Caresens means to identify whether there was significance different. Sinocare was used by eight (17.4%) participants while Caresens was used by thirty-eight participants (82.6%).

4.2.4.1 Comparison at Low glucose control level

Using the two sampled t-test, the output indicated that mean for Sinocare was 4.925 (*SD* =1.991) and for Caresen's was 5.163 (*SD*=0.382) the two tailed *p-value*= 0.4845 implying that there was no significance difference between the Sinocare and Caresens means.

4.2.4.2 Comparison at High glucose control level

Using two sampled t-test, the output indicated that mean for Sinocare was 13.363 (*SD* =0.348) and for Caresens was 11.952 (*SD*=1.543) the two tailed *p-value* = 0.0152 which is less than the standard significant level of 0.05 inferring that there is a significance difference between the Sinocare and Caresens means. After the removal of outliers, the mean for Sinocare was 12.418 (*SD* =0.626) and for Caresens was 12.96 (*SD*=0.207) the two tailed *p-value* = 0.0656 implying there is no significant difference between the two glucometers.

4.3 PHENOMENOLOGICAL STUDY RESULTS

Out of 20 questions 9 were analyzed qualitatively because they had sufficient responses as compared to the remaining questions (11). Data is usually saturated when a researcher samples from 5-25 participants (Creswell, 1988).

(Question 9-12 and 16-19)

1. Regarding knowledge of ISO 15189 and ISO 22870, two major themes were elicited namely total lack of knowledge and little knowledge regarding the policies.

Theme 1: Total Lack of knowledge regarding policies ISO 15189 and ISO 22870:

Majority of the respondents expressed lack of knowledge as shown below;

"I think it (ISO 15189) is related with the above am not sure" [Respondent 1]

"Am not sure but it (ISO 22870) is more applicable to lab personnel as they do point of care testing" [Respondent 12]

"I also don't know anything about this (ISO22870)" [Respondent 10]

(Long pause) "I don't know it (ISO22870)" [Respondent 3]

Theme 2: A little knowledge regarding policies ISO 9001:2015:

Half of the respondents demonstrated a little knowledge of 9001:2015 and related it to a quality management policy or statement

*It's (*9001:*2015) about quality management system, it is involving others, it also talks about risks, processes and engagement"[Respondent 5]*
*"It is (*9001:*2015) about the quality statement policy of the hospital" [Respondent 12]*

*"This (*9001:*2015) includes the quality management for every employee of the hospital" [Respondent 9]*

2. Regarding the role of the nurse in point of care testing therewere 3 major themes namely; Equipment maintenance, training and supervision as shown below

   Theme 1: Equipment maintenance:

   Majority of the respondents reported that their role was to maintain equipment as follows;

   "*I ensure that the all the equipment in the ward are calibrated, that I have adequate equipment like for example I ensure that the glucometer has enough strips and that my staff are more sensitized*" *[Respondent 7]*

   "*My role is supervision of staff and ensuring that all the equipment for the POCT are working appropriately. Making sure that all the staff are equipped with the relevant skills of operating the equipments this is done through regular CMEs in case of a new device introduced in the ward*"*[Respondent 9]*

   "*Ensuring that the glucose sticks and machines have been ordered, also ensuring that results are documented and interpreted and ensuring quality of the machines to ensure it's giving good reading and is calibrated by the biomedical people*"*[Respondent 11]*

Theme 2: Nurse training

Some of the respondents mentioned that they are key in training as shown by;

"*I have to ensure that the nurses are available and the nurses are knowledgeable. Documentation after doing it and intervention for example incase sugars are low, what interventions are to be done*" *[Respondent 5]*

"*I ensure adequate staff training and sensitization, I also ensure there should be correct documentation and interpretation and intervention of the result I also ensure equipments and devices are calibrated and work appropriately so that it does not give a false result*"*[Respondent 6]*

"*Ensuring people doing such procedures are qualified and well trained, Patient is explained to and consents to procedures, confidentiality this is privacy of patients, authentic result delivery and proper documentation, handing over and referral for continuity of care*" *[Respondent 1]*

Theme 3: Supervision

A few demonstrated this theme as evidenced by;

"*My role is to supervise; I ensure that all procedures and specimens are taken on time and results obtained on time" [Respondent 10]*

"*Ensuring that correct techniques are followed and patients are tested appropriately*" *[Respondent 12]*

3. Regarding understanding the process of POCT blood glucose testing 3 major themes were elicited namely; Total lack of knowledge on proficiency testing and calibration, a little knowledge on and lack of awareness that POCT testing is not in the nursing Council manual

   Theme 1: Respondents elicited total lack of knowledge of the terms proficiency testing and calibration

   Majority of the respondents did not demonstrate knowledge on what is meant by proficiency testing and calibration however most were able to explain what quality control is and associated it with maintaining a set of standards as evidenced by

   Proficiency is"*Proficiency, I have only used that word proficiency in light of HR not in lab , I don't know to be proficient is to be able to do what you should do in the way it is supposed to be done that is proficiency so my guess would be in this context of doing a laboratory assessment like this where your testing the patient at the bedside then the person doing that test should be able to, knows the procedure and is able to do the procedure the way it should be done*"*[Respondent 1]*

Calibration is "*Setting accurate marks or graduations on an equipment, the mark is always accurate and standard*" *[Respondent 2]*.

Calibration is "*it is putting a set of graduation on instrument for example the urine bag has calibrations like 100mls, 200 mls etc that is calibration*" *[Respondent 12]*.

Theme 2: A little knowledge of the term quality control

Majority of the respondents seemed to have an idea of quality control is but did not explain it very well as evidenced by;

Quality control is "*This is process of maintaining the original set standard through regular checkups and evaluation*" *[Respondent 9]*.

Quality control "*Quality control, quality control is about ensuring services rendered are within the set standards*" *[Respondent 10]*.

Quality control is "*It is where you maintain set standards by doing or performing a test to a particular equipment to ensure it is accurate and working" [Respondent 12]*.

Theme 3: Lack of awareness that the POCT glucose testing is not available in the nursing manual

Majority of the respondents explained in detail on what the process of obtaining blood glucose levels was as described in the nursing manual; however there is no such procedure in the nursing manual as shown by;

> *"Wash your hands first then set the trolley to ensure you have the glucometer and the glucose sticks, the lancets, swabs and you have a receiver for the sharps and the dirty swabs so the trolley is set, so wash your hands, put on the gloves and go to the patient's bedside explain the procedure to the patient when they are ready, swab with a dry swab, don't swab with a spirit swab, prick at the side of the finger not at the centre and not very deeply, get the glucometer with the glucose stick already in the glucometer, it will already show you the sign of putting in the blood, just slightly touch the finger with the blood onto the strip, it then sips and within*

15 seconds you just read, then now dispose accordingly, look if it is high, low or normal and tell the patient, so you dispose the sharp or lancet immediately, then dispose the swab and get another one to press on the finger to prevent bleeding and record the result"*[Respondent 4]*

"*First you have to prepare the patient psychologically and emotionally ,you also prepare the environment, prepare the equipment, to ensure that they are in good working order that one is supposed to be done daily and then in the equipments and supplies what we normally use is cleaning with spirit we prefer the middle finger because it is not painful and then you prick at the side after cleaning, allow it to dry and then you prick , you ensure that the glucose stick is inserted in the glucometer and it will blicker showing that it requires blood ,you wipe away the first drop, squeeze it again and the you take your blood sample and then you clean the side that you have pricked and then within seconds it will show your reading after that you are supposed to interpret like for children if it is low like for example like the neonates below 2mmol/dl you have to intervene by giving glucose per body kg. if it is high you also have to intervene by giving normal saline after that elaborate blood analysis is done with the blood gases you also find out the potassium measures and this will also give you reasons why the blood glucose is high and after that you also do further investigations, then you document"*[Respondent 5]

CHAPTER 5

5.0 DISCUSSION

5.1 Description of the performance specifications of the BGMS

During the time of this study, KNH had at least 306 glucometers of which 277 were functioning in 46 areas that were not under laboratory management. These are namely from general wards and special care wards including newborn unit (NBU), neonatal intensive care unit (NICU), burns unit, critical care units (CCUs), paediatric intensive care unit (PICU) and renal unit.

During the period of data collection, it was found that three (3) different types of glucose meters were being used in these wards.

Performance specifications

The three models of BGMs (Caresens, Sinocare and Accuchek) in use at KNH and all met the required FDA performance specifications for glucose meters.

Although all the three BGMs are not supposed to be used for critical care patients in this study 5 out of 46 sites (11%) were critical care units

Use of POCT devices in intensive care units can lead to misdiagnosis for both pediatric and adult population. (Cook A et al., 2009; Schifman and Nguyen, 2014)

Studies have shown increased risk of insulin dosing errors when BGMs are used to monitor glycemia in critical care patients (Karon.B, 2014)

Manufacturer's policies are different depending on the country/region. For Europe, European Norm (EN) international organization for standardization (ISO) 15197 (2015) defines a BGM to be accurate if ≥ 95% of results fall within ±15mg/dl (0.83mmol/L) of a laboratory result when blood glucose concentrations are < 100 mg/dl (5.56mmol/L) or within ±15% of the reference when the blood glucose concentrations are ≥ 100mg/dl (5.56mmol/L).

5.2 Quality management systems

In this study, only 40% of BGM users had seen an SOP for BGM use. This is likely the procedure contained in the BGM User manual which the participants mistakenly called the SOP. With a reliable quality management system POCT has the ability to improve patient

management. Moreover, laboratory system regulations are important for quality results which would be beneficial in the management of patients (NPHLS, 2016).

Establishment of quality management systems starts with policy and guiding documents including SOPs (BBSQ, 2019).

Absence of policy guiding documents has also been reported in other centres at the start of a quality management system (Khan AH et al., 2019). Policy documents would cover all aspects of point of care glucose testing, including SOPs (BBSQ, 2019).
Different countries have different guidelines/standards, in many of these, pathologists, clinical biochemists, general medical practitioners and nurses come together to form them (FDA, 2020)

5.3 Assessing the training and competence of BGM users

Training is important in ensuring quality of laboratory testing (BBSQ, 2019; FDA, 2020)

In this study, most participants were familiar with common quality terminologies such as assessment and audit. However, majority did not know laboratory specific quality terms such internal quality control which is supposed to be applied for BGM

Other reports show lack of knowledge of laboratory quality by POCT users (Khan AH et al., 2019, AACB, 2019) . Only 43% of the BGM users had received training which was offered by different trainers indicating there was no structured training. This is possible explanation for lack of knowledge of IQC and EQA. Training gap also identified in Pakistan study (Khan AH et al., 2019). Training, competence and certification of users are required in POCT quality management programs (Portogallo and Barlow, 2010; Kebede A et al 2016)

Some institutions only allow certified individuals to perform POCT (NPHLS, 2016; AACB, 2019)

An one hour lecture was recommended as sufficient time for POCT training, and this should also include a practical session (Jalavu P, 2020)
From the findings, 158 nurses responded that there was a procedure in the nursing manual instructing on how to perform glucose analysis using a glucometer, however after going through the manual there was no procedure. In UK, the nursing council requires the nurses to be knowledgeable and take part in regular competency assessment and should be able to elicit

expertise without being supervised (Nursing and Midwifery Council, 2008). It is therefore, important for the Nursing Council to include the procedure in the manual highlighting the importance of QMS and QA measures.

5.4 Maintenance and biosafety

Equipment maintenance is one of the laboratory quality system essentials (Audu RA et al., 2012; WHO, 2018)

In this study, two thirds of the respondents reported regular maintenance of BGM was done and it was carried out by mainly by the lab staff. Other studies reported absence of POCT machine maintenance records at baseline (Khan AH et al., 2019)

From the study, majority of the respondents (59.6%) said that the glucometer did not undergo regular assessments and audits. This is not contrary to Portogallo and Barlow (2010) carry out an audit every 2-3 months using criteria. This include checks for safety, performance of regular IQC and availability of QC solutions

From the findings majority of the respondents had not heard of the quality assurance IQC and EQA at 83.3% and 85.5% respectively

Almost all respondents reported availability of sharps box for biosafety and few incidents of sharps injuries.

5.5 Documentation

From the findings there is a special document to record glucose results. However, there is no special document to record unusual findings. POCT results are important for making therapeutic decisions. The report should have reference ranges, indicate the units of measurement and should indicate extremely high and low values (Shaw, 2015)

Unusual results should be documented and corrective action as well as preventive action should be applied after troubleshooting (Junker R et al., 2010; Marshall WJ et al., 2014)

5.6 Quality assurance

Quality assurance practices investigated were knowledge of quality standard terms such as IQC and EQA maintenance and frequency of users finding unusual results

Out of the 230 nurses 52.6% (n=121) have had an instance where they could not read the results clearly**.** Post analytical errors include misreading of glucose results either via over estimating or underestimating (Clarke and Foster, 2012)

The ISO standard 22870:2016 recommends that the BGM user should be trained using a framework that uses theory and practicals for IQC (Jalavu, 2020)

Moreover, it is was noted by the clinical biochemists in Australia that some areas in the hospital do not perform regular IQC and EQA (AACB, 2019)

In Germany medical laboratories performing glucose testing are required to participate in an EQA scheme and pass at least twice (German Medical Association, 2015). POCT is a form of laboratory test, therefore the same can be applied in the bed side testing.

FDA does not recommend using the criteria in ISO 15197 for BGMSs because it does not protect patients in the hospital setting. Within run precision and intermediate precision and linearity should be evaluated

According to Khan et al., (2019) some of the QA practices that could improve POC testing include:

h. Carrying out IQC and EQA regularly.
i. Carrying out regular assessments and audits
j. Standard operating procedures (SOPs) implementation for each test
k. Result reporting and recording.
l. Reporting performance of unusual results and occurrence management.
m. Regular equipment maintenance.
n. Implementation of safety and infection control measures.

5.7 Quality control analysis results

In this study out of the 92 control analyses (46x2), 7.6% and 13% results were unacceptable when consensus values and assigned values were used respectively. Two (2) participants (4.3%) obtained unacceptable with both low and high controls

Unacceptable results reported for 9%–10% of participants in a POCT EQA (Bietenbeck et al.,2018) . Training and recertification is usually recommended for staff persistently returning unacceptable results (Bietenbeck et al., 2018)

5. 8 Phenomenological data results

A total of twelve nurse managers in respective wards and clinics participated in this study. The respondents were from Prime care ward, orthopedic, general surgery, medical ward, specialized surgery, ophthalmology, burns unit, and obstetrics and gynecology department. 83.3% of the participants were female and 16.7% were male

From my knowledge there are no phenomenological studies that have been conducted to look at QMS and QA practices in nurses and few qualitative studies have been done.

Under quality management, the nurse managers did not know of the policies ISO 15189 and ISO 22870. According to Jalavu. P(2020) a successful POCT programme several aspects have to be considered such as organizational structure, training and competence of the operators, conducting proficiency testing and IQC and adequate documentation in accordance to ISO 22870

Nurses routinely perform POCT tests therefore it should be ensured that they have adequate knowledge according to the requirements of ISO 22870 by regular training (Robertson-Malt. S, 2008)

The nurse managers defined their role in POCT as equipment maintenance, training and supervision. From the interviews conducted the nurses had different roles and there seemed not to be a consensus on what was their role. In focus group discussions conducted by Dahm MR et al.,2017 and Rasti R et al.,2017), most participants pointed that POCT was important but since they were not included in the implementation of the POCT programs they were not contented with it

In understanding the process, the nurse managers did not quite fully understand what the terms quality control and proficiency testing were, there we can conclude that they were not well equipped with knowledge on quality assurance practices. A quantitative study conducted (Jalavu P, 2020) found that nurses had limited knowledge on quality control measures.

CONCLUSIONS AND RECOMMENDATIONS

CONCLUSIONS

The BGMs in use at KNH meet required performance specifications.

There is no policy document guiding POC glucose testing at KNH. Only 40% sites had an SOP for glucose testing

Only 43% BGM users had received training. Training is not standardized, and trainees are not certified.
There is a specific document to record blood glucose results however there is no adequate documentation that meets accreditation standards

Unacceptable control results were obtained at rate of 7.6% and 2 BGM users obtained unacceptable results at high and low glucose control levels.

RECOMMENDATIONS

KNH management should prepare policy guideline for POC glucose

Structured training program should be developed which incorporates competency assessment

Regular assessment of BGM testers using blind control material to identify staff requiring training

STUDY LIMITATIONS

Recall bias of the participants who gave no or incomplete responses

Obtaining sufficient liquid control was a challenge which limited the laboratory runs of the controls to five days only

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APPENDICES

APPENDIX 1: LABORATORY METHODS

Analysis of glucose using the POC device shall be done in each study site using commercial QC material These QC materials have low, and high glucose concentrations

QC ANALYSIS BY THE RESEARCHER

The low and high glucose concentration QC materials shall be used.

The QC materials will be run in the KNH's central biochemistry laboratory using a calibrated BGM twice a day (morning and afternoon) for 5 days.

The mean, CV and SD will be calculated for all the two control levels. The values obtained shall be the assigned values that will be used to compare with the results obtained by study participants.

APPENDIX 2: GANTT CHART

MONTH ACTIVITY	NOV 2019-APR 2020	MAY2020-AUG 2020	SEPT 2020-OCT 2020	NOV 2020	JAN 2020	FEB 2020	MAR- MAY 2021
Proposal writing							
Submission of proposal to ethical committee							
Data collection							
Data analysis							
Report writing							
Data presentation							
Dissemination of results							

APPENDIX 2: BUDGET

ITEM	QUANTITY	UNIT PRICE	TOTAL
QC material	3	4000	12,000
BGM tests	144	100	14,400
Pens	5	10	50
Exercise book	1	80	80
A4 fullscarps	2	60	120
Printing	10	200	2,000
Photocopy	250	100	25,000
Binding	10	200	2,000
Statistician	1	30,000	30,000
Research assistant	1	40,000	40,000
Internet service		2,000	2,000
Miscellaneous	1	3,000	3,000
		TOTAL	**130,650**

APPENDIX 3: LABORATORY REPORT FORM

NUMBER OF THE WARD/CLINIC ……

QC LEVEL	LOW	NORMAL	HIGH
WARD/CLINIC RESULT			
CONSENSUS MEAN			
CONSENSUS SD			
CONSESUS CV			
STUDY SITE SDI[a]			
IS THE SITE RESULT WITHIN ±3SD OF CONSENSUS MEAN?			
ASSIGNED GLUCOSE VALUE			
ASSIGNED GLUCOSE SD			
STUDY SITE SDI*			
IS THE SITE RESULT WITHIN ±3 SD OF ASSIGNED MEAN?			

SDI[a]- Standard Deviation Index= (Site result-consensus mean)/ Consensus SD

SDI*-Standard Deviation Index= (Site result- assigned glucose value)/ Assigned glucose SD

APPENDIX 4: CONSENT FORM FOR QUESTIONNAIRE

I, Fridah Muthoni Mukunya, am a student at the University of Nairobi conducting this research as a requirement for partial fulfillment of the requirements for the Masters of Science in Clinical Chemistry degree program. I wish to tell you about this research hoping you will agree to participate in it.

Background

Study Description

This research intends to assess the quality of blood glucose analysis by different glucose meters and users in KNH.

Your role

You have been identified to participate in this study because:

You are a nursing officer who performs glucose testing on patients in this unit. If upon reading the informed consent information you agree to take part in this research, you shall sign the consent and form and information will be obtained from you by means of a semi-structured questionnaire containing closed and open-ended questions.

In addition, you will be given 3 quality control and I will ask you to perform glucose testing on these QC materials using the glucometer in your ward. The material should be treated as patient sample hence all standard operating procedures for POCT glucose analysis should be adhered to. I shall record the results of the glucose tests that you will obtain.

Benefits of the study

The data collected will be used to find out the level of technique and quality assurance practices put in place to ensure quality blood glucose analysis. The study will be beneficial in that, it will provide objective evidence of the quality of glucose tests done at the point of care site. It may also identify gaps (if any) in the process of POCT for glucose, which can be used for continual quality improvement.

Risks

You will not be exposed to any risks or dangers when participating in this study The QC material does not pose biosafety risk.

Confidentiality

Only the researcher will have access to the obtained information. The data will remain under lock and key. Your name will not appear anywhere on the questionnaire. I will give you feedback on the quality of your QC tests. For this reason, I shall give your unit a unique number to use for identifying your QC results.

Participation

As a respondent, you will not receive any money or other rewards for participating in the study.

Voluntary participation

Your decision to be in this study is entirely voluntary. You have the right to withdraw your consent or stop participating at any one time. Refusing to participate in this study will not result in any penalty or loss of benefits which you are otherwise entitled.

Who to contact

If you have any questions regarding this study you may contact

<u>The Principal Investigator</u>

1. Fridah Muthoni Tel: 0711738183

<u>The Supervisors</u>

2. Professor Angela Amayo
   Department of Human Pathology,
   P.O Box 19676-00200, Nairobi
   Phone number: 0733617678
3. Dr. Abednego Ongeso
   School of Nursing Sciences, UON

P.O Box 19676-00200, Nairobi

Phone number: 0720775815

4. Mr. Alfred Gitau

   Department of Laboratory Medicine, KNH

   P.O Box 20723-00202, Nairobi

   Phone number: 0722452326

You can also contact The Secretary, Ethics and Research Committee at Kenyatta National Hospital (KNH/UON-ERC):P.O Box 20722 …..Phone Number 02072600-9 (Ext. 44102)

CONSENT DECLARATION

I consent to take part in the above-mentioned research by Fridah Muthoni Mukunya.I had the opportunity to ask questions and they have been answered satisfactorily. I understand what this research is all about and wish to participate in it.

Signature ———————————— Date ————————————

Witness_____ Date _____

APPENDIX 5: QUESTIONNAIRE

SERIAL NUMBER _____

a. Please tick/write your responses in the spaces provided
b. Please do not write your name anywhere in this questionnaire
c. Please ask for clarification for a question that is not well understood

SECTION 1: DEMOGRAPHICS

1. Age of the participant (please tick where appropriate)

a. 20-30 years ☐
b. 30-40 years ☐
c. 40-50 years ☐
d. >50 years ☐

2. Gender

Male ☐ Female ☐

3. How long have you worked in the ward/clinic
   a. Less than 1 year ☐
   b. 1-5 years ☐
   c. 5-10 years ☐
   d. more than 10 years ☐

SECTION 2: GENERAL INFORMATION

4. Name of the ward/clinic ……
5. What is the name of the glucometer used? (the manufacturing company)…….
6. How many glucometers are available?…….
7. How many glucometers are working?.....
8. How long has the working glucometer been in use in the ward/clinic?

☐

Less than 1 year

1-2 years ☐

Don't know ☐

It is not working ☐

SECTION 3: QUALITY MANAGEMENT

9. Have you ever come across the policy 9001:2015

   YES ☐ NO ☐

10. Have you heard about the policies ISO 22870 and ISO 15189?

YES ☐ NO ☐

11. Is there a policy document indicating responsibility or accountability of glucose testing i.e who will perform glucose testing using a glucometer?

    YES ☐ NO ☐

12. Do you have a Standard Operating Procedure (SOP),guiding glucose testing using a glucometer

    YES ☐ NO ☐

13. Is the SOP readily available in the ward/clinic

    YES ☐ NO ☐

14. Have you ever seen a glucometer's insert (of any glucometer you have used)?

    YES ☐ NO ☐

15. Have you ever read a glucometer's insert (of any glucometer you have used)?

    YES ☐ NO ☐

SECTION 4: SAFETY

16. Is there a sharp box readily available when you are doing an actual test?

YES ☐ NO ☐

17. Have you ever pricked yourself when undertaking a glucose test using a glucometer?

YES ☐ NO ☐

18. How often do you use personal protective equipment (PPEs) when carrying out glucose test using a glucometer

ALWAYS ☐ WHEN I GET ACCESS ☐ ONCE IN A WHILE ☐ NEVER ☐

19. Who has access to the glucometer?

EVERYONE INCLUDING STUDENTS ☐

NURSES ONLY ☐

NURSES AND DOCTORS ☐

20. Do you have any area designated for the storage of the glucometer?

YES ☐ NO ☐

SECTION 5: QUALITY ASSURANCE

21. Have you ever heard of the term IQC?

YES ☐ NO ☐

22. Have you ever heard of the term EQA?

YES ☐ NO ☐

23. Have you ever heard of the term quality control?

YES ☐ NO ☐

24. Have you ever heard of the term proficiency testing?

YES ☐ NO ☐

25. Have you ever heard of the term calibration?

YES ☐ NO ☐

26. Have you ever heard of the terms assessments and audits?

YES ☐ NO ☐

27. Are there regular assessments and audits of the glucometers

YES ☐ NO ☐

28. Does the glucometer undergo regular maintenance?

YES ☐ NO ☐

29. Who does the maintenance? (Please specify)…….

30. Are glucometer's results documented in a special document?

YES ☐ NO ☐

31. Are there instances where you could not read the results clearly from the display of the device, for example could not tell whether a result is 8.0 or 5.0 mmol/l

YES ☐ NO ☐

32. If unusual results are obtained, is there a document to report these findings?

YES ☐ NO ☐

33. Have you ever used the glucometer device on a critically ill patient?

YES ☐ NO ☐

SECTION 6: TRAINING ASSESSMENT

34. Have you ever been trained to use a glucometer in KNH?
    YES ☐ NO ☐
35. If YES who trained you?

LAB PERSONNEL ☐

VENDOR FROM THE MANUFACTURER ☐

OTHER (SPECIFY) …….

36. Have you ever undergone any competency assessment e.g taking an exam to measure your skills for POCT glucometer use?
    YES ☐ NO ☐
37. Have you ever attended any training curriculum for any glucose POC test ?

    YES ☐ NO ☐

If YES where was the training (please specify)

……..

38. Have you received a certificate to show that you can operate a glucometer?

    YES ☐ NO ☐

39. Is there a nursing manual available in the ward/clinic?

    YES ☐ NO ☐

40. Is there a procedure for instructing how to perform glucose analysis using a glucometer in the nursing manual?

    YES ☐

    NO ☐

APPENDIX 6: CONSENT FORM FOR THE PHENOMENOLOGICAL TOOL

I, Fridah Muthoni Mukunya, am a student at the University of Nairobi conducting this research as a requirement for partial fulfillment of the requirements for the Masters of Science in Clinical Chemistry degree program. I wish to tell you about this research hoping you will agree to participate in it.

Background

Study Description

This research intends to assess the quality of blood glucose analysis by different glucose meters and users in KNH.

Your role

You have been identified to participate in this study because:

You are a nurse manager and have a leadership role in the ward. If upon reading the informed consent information you agree to take part in this research, you shall sign the consent form and information will be obtained from you by means of a qualitative phenomenological tool.

Benefits of the study

The data collected will be used to find out the level of technique and quality assurance practices put in place to ensure quality blood glucose analysis. The study will be beneficial in that, it will provide objective evidence of the quality of glucose tests done at the point of care site. It may also identify gaps (if any) in the process of POCT for glucose, which can be used for continual quality improvement.

Risks

You will not be exposed to any risks or dangers when participating in this study.

Confidentiality

Only the researcher will have access to the obtained information. The data will remain under lock and key. Your name will not appear anywhere on the interview guide.

Participation

As a respondent, you will not receive any money or other rewards for participating in the study.

Voluntary participation

Your decision to be in this study is entirely voluntary. You have the right to withdraw your consent or stop participating at any one time. Refusing to participate in this study will not result in any penalty or loss of benefits which you are otherwise entitled.

Who to contact

If you have any questions regarding this study you may contact

<u>The Principal Investigator</u>

5. Fridah Muthoni Tel: 0711738183

<u>The Supervisors</u>

6. Professor Angela Amayo
   Department of Human Pathology,
   P.O Box 19676-00200, Nairobi
   Phone number: 0733617678
7. Dr. Abednego Ongeso
   School of Nursing Sciences, UON
   P.O Box 19676-00200, Nairobi
   Phone number: 0720775815
8. Mr. Alfred Gitau
   Department of Laboratory Medicine, KNH
   P.O Box 20723-00202, Nairobi
   Phone number: 0722452326

You can also contact The Secretary, Ethics and Research Committee at Kenyatta National Hospital (KNH/UON-ERC):P.O Box 20722 …..Phone Number 02072600-9 (Ext. 44102)

CONSENT DECLARATION

I consent to take part in the above-mentioned research by Fridah Muthoni Mukunya.I had the opportunity to ask questions and they have been answered satisfactorily. I understand what this research is all about and wish to participate in it.

Signature ———————————— Date ————————————

Witness_____ Date _____

APPENDIX 7: QUALITATIVE PHENOMENOLOGICAL TOOL

1. What is your age? .....
2. What is your gender? ……..
3. How long have you worked in the ward/clinic? (Probe) What is the name of the ward/clinic……..
4. What is the brand name of the glucometer used in this ward/clinic……..
5. How many glucometers are here (Probe) how many glucometers are working and how many are not working? .....
6. How long has the working glucometer been in use in this ward/clinic? .....
7. Are there policy documents for any nursing process available in the ward/clinic? (Probe) what are the nursing processes that have policy documents?
   ……
   ……
   ……
8. What are the nursing processes without policy documents (Probe) do you suggest that they should have them and why?
   ……
   ……
   ……
9. Could kindly explain the policy 9001:2015
   ……
   ……
   ……
10. Could you kindly explain the policy ISO 22870
    ……
    ……
    ……
11. Could you kindly explain the policy ISO 15189

    ……
    ……
    ……
    ……
    .....

12. What is your role in ensuring quality of POCT in your ward/clinic?

    ……
    ……
    ……

13. What does IQC stand for? (Probe) what does it entail?

    ……
    ……
    ……

14. What does EQA stand for? (Probe) what does it entail?

    ……
    ……
    ……

15. Who performs IQC and EQA on the glucometers and are the procedures done regularly? (Probe) in your opinion, who should carry out the IQC and EQA procedures?

    ……
    ……
    ……

16. Could you kindly explain what quality control is?

    ……
    ……
    ……

17. Could you kindly explain what proficiency testing is?

    ……
    ……
    ……

18. Could you kindly explain what calibration is?

    ……
    ……
    ……

19. Could you kindly explain the process (in the nursing manual) of getting blood glucose levels of a patient using a glucometer

    ……
    ……
    ……

20. What is competency assessment (Probe) in your opinion, who should do competency assessment for POC glucose analysis and why?

    ……
    ……
    ……

APPENDIX 8: MEASURES OF SAFETY AGAINST COVID-19

Due to the current COVID-19 pandemic, I intend to take the following measures in order to protect the participants, research assistant and myself from contracting the disease.

1. I will have one research assistant who will be involved in administering questionnaires/phenomenological tools to the participants and also giving QC material for analysis. I will ensure that he/she is equipped with information regarding methods of transmission, clinical presentation and preventative measures of the disease.
2. The research assistant and I will use a surgical facemask throughout the process of study participant recruitment, administration of questionnaires/phenomenological tools, interview and analysis of QC material.
3. During this process of data collection we will maintain physical distance of one meter between the participant and the research assistant or the principal investigator.
4. The research assistant and I will also practice hand washing/hand sanitizing before and after every QC analysis procedure. The waste materials after QC testing will be safely discarded in the clinical waste bins available at each study site.
5. The participants will be provided with hand sanitizer to sanitize their hands before and after handling the consent documents and study questionnaires/phenomenological tools.